IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

MICHELE GRISHAM, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 21-cv-00656-SRB
	)	
COVIDIEN, INC., et al.,	)	
	)	
Defendants.	)	

ORDER

Before the Court is Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint. (Doc. #26.) For the reasons set forth below, the motion is DENIED.

I. FACTUAL BACKGROUND

The following allegations are taken from Plaintiff Michele Grisham and Brenda Thompson's ("Plaintiffs") First Amended Complaint. (Doc. #23.) Additional allegations relevant to the pending motion are discussed in Section III.[1]

Defendant Covidien, Inc., Covidien Holding, Inc., Covidien, LLC, Medtronic USA, Inc., Tyco International LTD, and Sofradim Corp. (collectively, "Defendants") designed, manufactured, marketed, and/or sold a hernia mesh product known as Symbotex. Symbotex is used in the treatment and repair of hernias. On May 3, 2016, a surgeon implanted Defendants' Symbotex product into David Grisham's ("Dececent") abdominal wall. The procedure was intended to reinforce the repair of Decedent's hernia defect.

Following the procedure, Decedent began having abdominal pain. In approximately September 2017, Decedent felt his mesh repair had failed. On November 17, 2017, the

[1] Only those facts necessary to resolve the pending motion are discussed below, and they are simplified to the extent possible. All citations to the record refer to the pagination automatically generated by CM/ECF.

University of Kansas Hospital diagnosed Decedent with a partial small bowel obstruction. After consulting with a surgeon, Decedent underwent surgery to repair his recurrent incisional hernia on December 6, 2017.

On December 14, 2017, Decedent began experiencing abdominal pain. The pain became severe and an ambulance was called to Decedent's home. Upon arrival, ambulance personnel pronounced Decedent dead at the scene. Decedent was 33 years old at the time of his death. An autopsy confirmed Decedent's cause of death as complications from acute peritonitis. The autopsy found in part that Decedent's "mesh had caused significant adhesions to develop in the area and became loosened, which ultimately allowed the bowel to become strangulated and trapped, and eventually, perforated. The perforation of the bowel allowed fecal material and bacteria to go into the abdominal cavity leading to widespread infection/peritonitis." (Doc. #23, ¶ 73.)

On September 10, 2021, Plaintiffs—as the heirs of Decedent—filed this lawsuit. The First Amended Complaint is brought against Defendants and several other entities. The First Amended Complaint asserts three claims: Count I: Strict Liability—Defective Design; Count II: Failure to Warn; and Count III: Negligence. Plaintiffs seek various forms of relief, including actual and punitive damages.

Defendants now move to dismiss the First Amended Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Defendants argue in part that the "allegations regarding [Decedent's] injuries relate only to tissue adhesion, infection, and organ injury. The instructions that accompany Symbotex warn of precisely these potential complications." (Doc. #27, p. 6.) Defendants also argue that the First Amended Complaint fails to adequately

allege "which entities are responsible for what supposed wrongdoing." (Doc. #27, p. 6.) Plaintiffs oppose the motion, and the parties' arguments are addressed below.

II. LEGAL STANDARD

Rule 12(b)(6) provides that a defendant may move to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss [for failure to state a claim], a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).[2] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ash v. Anderson Merchs., LLC*, 799 F.3d 957, 960 (8th Cir. 2015) (quoting *Iqbal*, 556 U.S. at 678). When deciding a motion to dismiss, "[t]he factual allegations of a complaint are assumed true and construed in favor of the plaintiff, even if it strikes a savvy judge that actual proof of those facts is improbable." *Data Mfg., Inc. v. United Parcel Serv., Inc.*, 557 F.3d 849, 851 (8th Cir. 2009) (citations and quotations omitted).

III. DISCUSSION

A. Count I: Strict Liability—Defective Design

Count I asserts a claim for strict liability/defective design. "To recover under a theory of strict liability in tort for defective design, a plaintiff must establish (1) the defendant sold the product in the course of its business; (2) the product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a

[2] A court may also consider materials embraced by the complaint. *See Ashanti v. City of Golden Valley*, 666 F.3d 1148, 1151 (8th Cir. 2012) ("Though matters outside the pleading may not be considered in deciding a Rule 12 motion to dismiss, documents necessarily embraced by the complaint are not matters outside the pleading."). Here, both parties rely on Symbotex's instructions for use because the instructions are embraced by the First Amended Complaint.

manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of the defective condition that existed when the product was sold." *Cobbins v. J.E. Dunn Constr. Co.*, Case No. 15-0031-CV-W-ODS, 2016 WL 6440139, at * 5 (W.D. Mo. Oct. 28, 2016) (citing *Linegar v. Armour of Am., Inc.*, 909 F.2d 1150, 1152-53 (8th Cir. 1990) (applying Missouri law)).[3]

Defendants argue that Plaintiffs' defective design claim is barred by comment k to § 402A of the Restatement (Second) of Torts, which has been adopted by Missouri. Comment k "recognizes that certain useful and desirable products are, under the present state of human knowledge, incapable of being made safe for their intended and ordinary use." *Racer v. Utterman*, 629 S.W.2d 387, 393 (Mo. App. E.D. 1981). If such products are "accompanied by proper directions and warning," the products are "not defective nor . . . unreasonably dangerous." *Id.*; *see also Joyce v. Davol, Inc.*, No. 4:15-CV-468 JAR, 2016 WL 775183, at * 2 (E.D. Mo. Feb. 29, 2016).

Defendants argue the defective design claim should be dismissed under comment k because "the Symbotex mesh was accompanied by proper directions and warning of cautioning of the very risks Plaintiffs claim materialized." (Doc. #27, p. 12.) According to Defendants, the Symbotex instructions "warned that Symbotex is associated with potential complications like 'adhesion, 'infection,' and 'inflammation,' and that risks included 'organ injury (including bowel and visceral injury)' and 'bowel obstruction'—precisely the dangers of which Plaintiffs complain." (Doc. #27, p. 12) (citation omitted). In response, Plaintiffs argue that comment k is an affirmative defense which should not be decided on a motion to dismiss. Plaintiffs also contend that "Defendants conveniently ignore key sections of Plaintiffs' First Amended Complaint asserting that

[3] The Court has diversity jurisdiction over this case. *See* 28 U.S.C. § 1332. The parties agree, and the Court finds, that Missouri substantive law applies to each claim asserted by Plaintiffs.

Defendants failed to warn that these issues could lead to mesh disruption, mesh migration, and death, the injuries Decedent ultimately suffered in this instance and which are absent from" the instructions. (Doc. #29, p. 7.)

Upon review, the Court finds that Plaintiffs' defective design claim is not barred by comment k. Courts have held that "comment k is an affirmative defense and its applicability must be determined by the trial courts on a case-by-case basis." *Pollard v. Ashby*, 793 S.W.2d 394, 400 (Mo. App. E.D. 1990*); see also In re NuvaRing Prods. Liab. Litig.*, No. 4:08–MD–1964 RWS, 2013 WL 3716389, at * 9 (E.D. Mo. July 12, 2013).

As explained by one court:

> [a] design defect claim's 'unreasonably dangerous' inquiry involves a two-step analysis to evaluate the possible liability of a manufacturer . . . 1) whether the product is so unsafe that marketing at all is 'unreasonably dangerous per se;' and 2) if not, whether the product has been introduced into the stream of commerce with insufficient safeguards and is thereby 'unreasonably dangerous as marketed.' The first prong of the inquiry involves a balancing process in which the product's utility is weighed against the potential harmful effects caused by its introduction into commerce. Only if the product is determined not 'unreasonably dangerous per se' does the analysis proceed to the 'unreasonably dangerous as marketed' inquiry, at which point Comment k becomes applicable. Because the prerequisite 'unreasonable dangerous' determination involves weighing of evidence, consideration of the applicability of Comment k's bar to Plaintiff's strict liability design defect claim is not appropriate in a motion to dismiss.

Anastasi v. Wright Med. Tech., Inc., 16 F. Supp. 3d 1032, 1041 (E.D. Mo. 2014).

Defendants' reply brief reiterates that comment k warrants dismissal based "on the face" of the First Amended Complaint and the Symbotex instructions. (Doc. #40, pp. 4-7.) However, at this early stage of litigation, the Court agrees with Plaintiffs that they have alleged harms which are arguably absent from the Symbotex instructions. Following discovery, the Court will be in a better position to weigh all the evidence along with the applicable factors. *See Anastasi*, 16 F. Supp. 3d at 1041. The Court also finds that Plaintiffs have adequately pled that

Defendants' instructions and warnings were not adequate. Consequently, the Court denies Defendants' motion to dismiss Count I for defective design.

B. Count II: Failure to Warn

Count II asserts a claim for failure to warn. "The elements of a cause of action for strict liability failure to warn are: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. banc 2011).

Defendants argue this claim is barred by the learned intermediary doctrine. Under the learned intermediary doctrine "a manufacturer of prescription drugs or medical devices has a duty to warn a physician of the risks involved with its product. The physician then acts as a 'learned intermediary' between the manufacturer and the patient so that any warning given to the physician is deemed a warning to the patient." *Chole v. Boston Scientific Corp.*, No. 4:19-CV-02976 JAR, 2020 WL 1853266, at * 6 (E.D. Mo. Apr. 13, 2020). To avail itself of the learned intermediary doctrine, a manufacturer must establish that it "properly warn[ed] the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. App. E.D. 1999) (citations and quotations omitted).

Defendants argue Plaintiffs "offer no cognizable allegations beyond threadbare recitals that Defendants did not adequately warn [Decedent's] provider of the risks that might

accompany Symbotex." (Doc. #27, p. 13.) The Court disagrees. As explained in Plaintiffs' opposition brief, the First Amended Complaint includes the following allegations:

- That the tensile strength of the Symbotex mesh was inadequate, leading to mechanical failure of the mesh;
- That mechanical failure of the mesh and mesh disruption can lead to migration or contracture of the mesh and erosion into adjacent organs;
- That Defendants did a study in or around 2014 revealing Symbotex had an unreasonably high rate of mechanical failure but concealed the results from regulatory authorities and healthcare providers;
- That the mesh in Decedent, due to the weakened material and inflammatory properties of the material used in the Symbotex mesh, broke away from the abdominal wall (mesh disruption), became loosened in the area, ultimately leading to injury of the bowel and Decedent's death;
- That Defendants failed to property warn Decedent and his healthcare providers of the *heightened* risks of mechanical failure, fixation failure, and mesh migration associated with the Symbotex product;
- That Defendants failed to warn Decedent's healthcare providers that the material of the Symbotex mesh had not passed tensile strength or burst strength testing necessary to demonstrate the mechanical integrity of the product;
- That Defendants failed to properly and adequately warn or instruct Decedent and his health care providers as to such risks of the Symbotex Mesh and how and why the [instructions] were inadequate to inform Decedent's physicians of such risks;
- That Defendants failed to properly and adequately warn and instruct Decedent and his health care providers on the inadequate research and testing that was done of the Symbotex Mesh; and
- That Decedent's physician was unaware of the defects and dangers of the Symbotex Mesh and was unaware of the frequency, severity, and duration of the defects and risks associated with it.

(Doc. #29, pp. 8-9) (citations omitted).[4] At the motion to dismiss stage, these and the additional allegations in the First Amended Complaint are sufficient to withstand Defendants' learned intermediary argument.[5]

[4] Plaintiffs' opposition brief inaccurately cites the page and paragraph numbers from the First Amended Complaint.

[5] Defendants' reply brief argues in part that "[c]learly, physicians would understand the broad implications of the warnings given[.]" (Doc. #40, p. 7.) However, the knowledge and/or understanding of physicians with respect to the warnings given or not given under the facts of this case is not proper at the motion to dismiss stage.

Defendants also argue that Plaintiffs failed to adequately allege causation, namely, "that any different or additional warnings would have altered the treatment decisions made by [Decedent's] physician." (Doc. #27, p. 13; Doc. #40, p. 8.) However, the First Amended Complaint alleges that "[i]f Decedent and/or his physicians had been properly warned of the defects and dangers of the Symbotex device, and of the frequency, severity and duration of the risks associated with the Symbotex device, Decedent's healthcare providers would not have used the Symbotex mesh, and Decedent would not have consented to allow the device to be implanted." (Doc. #23, p. 30, ¶ 110.) This allegation, along with those quoted above, sufficiently plead causation. For these reasons, Defendants' motion to dismiss Count II for failure to warn is denied.

C. Count III: Negligence

Count III asserts a negligence claim. Under Missouri law, a negligence claim has the following elements: "[1] the defendant had a duty to protect the plaintiff from injury, [2] the defendant failed to perform that duty, and [3] the defendant's failure proximately caused injury to the plaintiff." *L.A.C. v. Ward Parkway Shopping Ctr., Co., L.P.*, 75 S.W.3d 247, 257 (Mo. banc 2002) (citations and quotations omitted). Defendants argue this claim should be dismissed because the First Amended Complaint merely recites "these elements accompanied by generic assertions." (Doc. #27, p. 14.) Defendants argue Plaintiffs failed to "identify specific conduct by particular Defendants that breached the standard of care." (Doc. #27, p. 14.)

Upon review, the Court rejects these arguments. Among other allegations, the First Amended Complaint alleges that "Defendants had a duty to individuals, including to Decedent, to use reasonable and ordinary care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and

warnings for the Symbotex device, as well as in the instruction and training of physicians to implant the Symbotex device and/or to properly treat complications associated with the Symbotex device." (Doc. #23, ¶ 116.) Plaintiffs allege that Defendants breached that duty in various ways, including by failing to design Symbotex in a way to avoid unreasonable risks to patients, by failing to properly test and study Symbotex, and by failing to adequately instruct and warn physicians of risks associated with the use of Symbotex. Finally, Plaintiffs allege damages caused by the breach, including Decedent's death. Under these circumstances, Plaintiffs have adequately pled the elements of a negligence claim. Defendants' motion to dismiss Count III for negligence is denied.

D. Punitive Damages

The First Amended Complaint requests various forms of relief, including an award of punitive damages. Defendants argue that "Plaintiffs' allegations regarding punitive damages [are] inadequately pleaded" under Federal Rule of Civil Procedure 9(b). (Doc. #27, p. 15.) Rule 9(b) states that when "alleging fraud . . . a party must state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). This requires a plaintiff to "plead the who, what, when, where, and how" of the alleged fraudulent conduct. *Summerhill v. Terminix, Inc.,* 637 F.3d 877, 880 (8th Cir. 2011) (quotations omitted).[6]

The Court finds that Plaintiffs have adequately pled their request for punitive damages. Although Rule 9(b) imposes a heightened pleading standard for fraud or mistake, it also provides that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The First Amended Complaint alleges that Defendants'

[6] Defendants argue that Plaintiffs do not adequately plead fraud, but punitive damages are not limited to cases involving fraudulent conduct. Punitive damages may be awarded based on "a wanton, willful, or outrageous act, or from reckless disregard for an act's consequences such that an evil motive may be inferred." *Darks v. Jackson Co.*, 601 S.W.3d 247, 259 (Mo. App. W.D. 2020).

conduct "shows willful misconduct, malice . . . wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages." (Doc. #23, ¶ 135.) Based on the allegations discussed throughout, Plaintiffs have adequately pled malice, wantonness, and other conduct which would support an award of punitive damages. Consequently, Defendants' motion to dismiss and/or strike the punitive damages allegations is denied.[7]

E. Group Pleading

In general, "[a] complaint which lumps all defendants together and does not sufficiently allege who did what to whom, fails to state a claim for relief because it does not provide fair notice of the grounds for the claims made against a particular defendant." *Tatone v. SunTrust Mortg., Inc.*, 857 F. Supp. 2d 821, 831 (D. Minn. 2012). Defendants argue the First Amended Complaint should be dismissed because it impermissibly "lumps all defendants together." (Doc. #27, p. 15.) Defendants contend the First Amended Complaint and "its blunderbuss approach fails to allege which defendants are responsible for the various essential elements of their claims." (Doc. #27, p. 16; Doc. #40, pp. 8-9, 10-13.)

Upon review, the Court rejects this argument. The First Amended Complaint is not "a shotgun pleading in which a plaintiff brings every conceivable claim against every conceivable defendant, resulting in a cause of action so general that it fails to put the various defendants on notice of the allegations against them." *Phyllis Schlafly Revocable Trust v. Cori*, 512 F. Supp. 3d 916, 924-25 (E.D. Mo. 2021) (citations and quotations omitted). Plaintiffs have alleged that all Defendants designed, manufactured, sold, tested, researched, marketed, distributed, and/or

[7] Defendants' initial brief argues that Plaintiffs' punitive damages allegations were inadequately pled. Defendants' reply brief states that "this Court need take no action on the punitive damages allegations standing alone." (Doc. #40, p. 10.) The foregoing rulings are made to clarify the record and avoid future disputes regarding such allegations.

otherwise engaged in acts or omissions which caused harm to Decedent. These allegations are sufficient to put each Defendant on fair notice of the claims against it. As such, and at this stage of litigation, the Court accepts Plaintiffs' representation that they "have done research and only named Defendants they have a good faith basis to believe had some involvement with the Symbotex Mesh." (Doc. #29, p. 15.) Defendants' group pleading arguments are therefore denied.

IV. CONCLUSION

Accordingly, Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint (Doc. #26) is DENIED. Defendants' request for oral argument is denied as unnecessary and as moot.

IT IS SO ORDERED.

/s/ Stephen R. Bough
STEPHEN R. BOUGH
UNITED STATES DISTRICT JUDGE

Dated: February 9, 2022